

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicants: Simpson, et al.  
Appl. No.: 10/659,760  
Conf. No.: 4834  
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Title: WIRELESS MEDICAL DATA COMMUNICATION SYSTEM AND METHOD  
Art Unit: 3686  
Examiner: Nguyen, Hiep Van  
Docket No.: 6066US BX2009T00920 (3712044-01151)

Commissioner for Patents  
P.O. Box 1450  
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**PRE-APPEAL BRIEF REQUEST FOR REVIEW**

Examiners:

Introduction

This Request and the following remarks are in response to the final Office Action dated February 18, 2011 (“the final Office Action”). Applicants respectfully submit that the final Office Action rises to the level of clear error, making this case proper for pre-appeal review. This Request is filed contemporaneously with a form PTO/SB/33, “Pre-Appeal Brief Request for Review” and form PTO/SB/31, “Notice of Appeal.” Please charge Deposit Account No. 02-1818 for the Notice of Appeal fee set forth under 37 C.F.R. §41.20(b)(1) and any other fees due in connection with this Request.

Claims 1 to 53 and 58 are pending. In the final Office Action, Claims 1 to 9, 13 to 25, 29 to 50 and 58 were rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Pat. No. 6,641,533 to Causey III et al. (“Causey”) in view of U.S. Pat. No. 5,827,180 U.S. Pat. Pub. No. 2002/0038392 (“*De la Huerga*”). Claims 10 to 12, 26 to 28 and 51 to 53 were rejected under 35 U.S.C. 103(a) as being unpatentable over *Causey*, *De la Huerga* and U.S. Pat. No. 6,795,421 to Heinonen et al. (“*Heinonen*”). Applicants note that the Advisory Action dated April 29, 2011 did not address the arguments in the Response to the final Office Action dated April 4, 2011.

35 U.S.C. Section 103(a) Rejections of Claims 1 to 9, 13 to 25, 29 to 50 and 58

Independent claim 1 is directed to a system for reporting on integrity of a wireless communication link within a healthcare facility including, in part:

software installed on the wireless remote device, the software configured to report upon the integrity of the wireless communication link by: (i) sending a signal to the wireless communication link, (ii) waiting a predetermined amount of time for a response to the signal sent to the wireless communication link, and (iii) generating a time-out output that indicates loss of the wireless communication link when the response is not received within the predetermined amount of time. (emphasis added).

Applicants respectfully submit that *Causey* and *De la Huerga*, alone and in combination, fail to disclose or suggest a system including a wireless remote device having software configured to report upon the integrity of the wireless communication link by: (i) sending a signal to the wireless communication link (ii) waiting a predetermined amount of time for a response to the signal sent to the wireless communication link, and (iii) generating a time-out output that indicates loss of the wireless communication link when the response is not received within the predetermined amount of time.

The final Office Action at page 3 acknowledges that *Causey* does not disclose the wireless remote device having software configured according to claim 1. The final Office Action at page 3 instead cites to *De la Huerga* for such disclosure. In particular, the final Office Action at pages 3, 9 and 10 cites to paragraphs [0223] [0325] to [0327], [0041] and [0221] of *De la Huerga* for the disclosure of a wireless remote device having software configured to report on the integrity of a wireless communication link by performing (i), (ii), and (iii) of claim 1. However, for the reasons discussed below, Applicants respectfully disagree and submit that none of the cited paragraphs of *De la Huerga* (or any of its other paragraphs) discloses or suggests a wireless remote device with software configured to report upon the integrity of a wireless communication link by performing (i), (ii), and (iii) of claim 1.

For example, paragraph [0223] of *De la Huerga* (cited to at pages 9 and 10 of the Response to Arguments section of the final Office Action) discloses, in pertinent part:

a pump unit that includes a line sensing switch 128 that detects whether a line is de-linked from a pump unit. The pump 100a may be programmed to transmit a message to controller 260 indicating that a de-linking event has occurred.

Based on the above-quoted disclosure of *De la Huerga*, it appears that the final Office Action at pages 9 and 10 is interpreting the programming of *De la Huerga*'s pump 100a (which is programmed to determine the absence or presence of an IV line via line switch 128) as the device having software that reports upon the integrity of the wireless link of claim 1. Applicants

respectfully submit that this interpretation is incorrect and that such an interpretation clearly fails to meet claim 1.

Paragraph [0223] of *De la Huerga* does not disclose or suggest that pump 100a (i) sends a signal to a wireless communication link, (ii) waits for a response to the signal sent to the wireless communication link, (ii) and if that signal is not received within a certain time, then pump 100a generates a time-out output that indicates loss of a wireless communication link. Instead, *De la Huerga*'s paragraph [0233] teaches that if pump 100 determines that a fluid line (e.g., IV line 150a) is disconnected from pump 100a, pump 100a can transmit a message to controller 260 indicating that that the fluid line has been removed from the pump 100a. Thus, pump 100a does not send a signal to a wireless communication link, but instead receives a signal indicating that a fluid line is linked to the pump 100. Pump 100a also does not generate a time-out output that indicates loss of a wireless communication link, but instead generates an output sent to controller 260 indicating that a fluid line has been disconnected from pump 100a.

Applicants respectfully submit that (i) the signal indicating a fluid line has been removed from pump 100a does not meet a signal indicating a wireless communication link has been lost, and (ii) the determination of whether a fluid line is linked to pump 100a does not meet sending a signal to a wireless link, and waiting for a response to the signal to determine whether a wireless link has been lost. Indeed, the determination in *De la Huerga* of whether a fluid line is connected to pump 100a is made via a mechanical switch 150, which appears to be sending a signal to the pump 100a. See, *De la Huerga*, paragraph [0147]. Thus, if the Office Action has interpreted the removal of a line as the loss of a wireless link of claim 1 (which is a strained interpretation), than pump 100a fails to meet claim 1 because pump 100a is not sending a signal to a fluid line (i.e., interpreted as the wireless link), but rather, the pump is receiving a signal from the fluid line that indicates that the fluid line is no longer connected to the pump 100a. *Id.* Again, this is a strained reading because no loss of a wireless communication link has occurred.

Regarding paragraphs [0325] to [0327] of *De la Huerga*, Applicants respectfully submit that these paragraphs also do not teach or suggest software configured to: (i) send a signal to a wireless communication link, (ii) wait a predetermined amount of time for a response to the signal sent to the wireless communication link, and (iii) generate a time-out output that indicates loss of the wireless communication link when the response is not received within the predetermined amount of time. Instead, these cited paragraphs teach a controller 260 that can

monitor a channel 255 for a message indicating whether an IV line 150 is still attached. See, *De la Huerga*, paragraph [0325]. If the controller 260 does not receive the message within a certain time, the controller may activate an alert. *Id.* Thus, controller 260 waits for a message indicating whether the IV line is still attached to a pump 100a, and not for a message indicating that a wireless communication link has been lost as found in claim 1. Further, the output that is generated by controller 260 after waiting a certain amount of time and not receiving a response (i.e., the alarm), is not an indication of a loss of a wireless link as found in claim 1, but is instead an indication that an IV line is still attached to a pump when it should not be. *Id.*

Regarding paragraph [0041] of *De la Huerga*, paragraph [0041] discloses:

In one use of the controller, the badge records information from the wristband, the IV bag information device, and in some cases an identifier placed on the IV pump (or a pump module when the pump can be used with more than one line). All of this information is transferred to the controller (e.g. via wireless communication). (emphasis added).

While paragraph [0041] of *De la Huerga* discloses a badge (e.g., PDA) that transfers information to a controller via wireless communication, nothing in this paragraph discloses or suggests that the badge includes software configured to: (i) send a signal to a wireless communication link, (ii) wait a predetermined amount of time for a response to the signal sent to the wireless communication link, and (iii) generate a time-out output that indicates loss of the wireless communication link when the response is not received within the predetermined amount of time. Paragraph [0041] is deficient with respect to these features of claim 1.

Regarding paragraph [0221] of *De la Huerga*, paragraph [0221] discloses:

In addition, controller 260 may start a timer to time out a period during which authentication must be completed for controller 260 to authorize operation of the unit according to the changed protocol. Where authentication is not successfully completed within the time out period, it is contemplated that controller 260 would not allow the changed protocol to begin, may provide another message via display 266 indicating that the change would not occur and may also log the change attempt in a remote database for future consideration. (emphasis added).

While the above-quoted paragraph of *De la Huerga* discloses that controller 260 may wait for a response from a user of a pump to determine whether that user is authorized to make a change to the pump, nothing in the paragraph discloses or suggests software that reports upon the integrity of a wireless communication link at all, let alone software that reports upon the integrity of a wireless communication link by: (i) sending a signal to the wireless communication link, (ii)

waiting a predetermined amount of time for a response to the signal sent to the wireless communication link, and (iii) generating a time-out output that indicates loss of the wireless communication link when the response is not received within the predetermined amount of time. Again, paragraph [0221] is also deficient with respect to these features of claim 1.

For at least the above reasons, Applicants respectfully submit that independent claim 1 and its dependent claims 2 to 9 and 13 to 17 are patentably distinguished over *Causey* and *De la Huerga*. Independent claims 18, 33 and 44 each include similar elements to independent claim 1. Applicants accordingly respectfully submit that for at least the reasons given above with respect to independent claim 1, independent claims 18, 33 and 44 and their respective dependent claims 19 to 25, 29 to 50, and 58 are patentably distinguished over *Causey* and *De la Huerga*.

35 U.S.C. Section 103(a) Rejection of Claims 10 to 12, 26 to 28 and 51 to 53

The patentability of independent claims 1, 18, 33 and 44 renders the separate obviousness rejections of claims 10 to 12, 26 to 28 and 51 to 53 over *Causey*, *De la Huerga* and *Heinonen* moot.

At least Dependent Claims 16, 17, 31, 32, 42 and 43 Include Additional Patentable Features

Applicants additionally respectfully submit that for the reasons discussed in detail in the Response to final Office Action of February 22, 2010 and to the Advisory Action dated April 30, 2010 (filed at the Patent Office on July 7, 2010), at least dependent claims 16, 17, 32, 42 and 43 provide additional patentable features over the prior art.

Respectfully submitted,

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